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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,852	09/05/2003	Neville Alleyne	ALLEYN2.001A	7244
20995	7590	12/28/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP 2040 MAIN STREET FOURTEENTH FLOOR IRVINE, CA 92614			BAXTER, JESSICA R	
			ART UNIT	PAPER NUMBER
			3733	

DATE MAILED: 12/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/655,852	ALLEYNE, NEVILLE	
	<b>Examiner</b>	<b>Art Unit</b>	
	Jessica R. Baxter	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-17 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-17 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 05 September 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____.   |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07222004, 12082003</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|   | 6) <input type="checkbox"/> Other: _____.                                   |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims 1-4 are rejected under 35 U.S.C. 102(e) as being anticipated by U. Patent No. 6,592,625 to Cauthen.

Cauthen discloses a biocompatible seal device comprising: a solid sheet (20,22), the sheet having a protruding portion configured to fit in an opening in a disk annulus (14); wherein the protruding portion is substantially circular (FIG. 4B); wherein the sheet is substantially pliable (FIGS. 11A-11D); wherein the sheet includes a radiopaque material (Column 5, lines 19-40).

3. Claims 13-16 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,007,562 to Harren et al.

Harren discloses a biocompatible seal device comprising: a sheet (19), the sheet having a first surface portion contoured to cover an opening (102) and a second surface portion wherein the sheet is; wherein the sheet is substantially pliable; wherein at least a

portion of the sheet is received into the opening (FIG. 6); wherein the sheet includes a radiopaque material.

Regarding the limitations “ contoured to align with the exterior surface of the spinal disk” and “composed of a material which inhibits the postoperative migration of surgically introduced bone morphogenic protein into surrounding tissue”, these limitations do not add any structure to the device as claimed. The device of Harren is capable of performing these functions as claimed since it is a pliable seal device that could conform to the shape of tissue surrounding the puncture.

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 6-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '625 in view of US PG-PUB 2002/0123750 to Eisermann et al.

Cauthen discloses a method of surgery, the method comprising: resecting a posterior lateral herniation in a spinal disk annulus; forming an opening in the annulus in a posterior lateral location (Column 2, lines 29-57); sealing the opening with a biocompatible seal wherein the seal is positioned to cover the opening (FIGS. 7A-8B); wherein sealing the opening includes positioning a protruding portion of the seal into the opening (FIG. 8B).

Cauthen discloses the claimed invention except for introducing a bone morphogenic protein into the opening. Eisermann teaches that bone morphogenic proteins are used in implants in order to induce the formation of bone (Paragraphs 0014-0015 and 0038). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the method of Cauthen with the step of introducing bone morphogenic protein since it is known in the art to use bone morphogenic protein to induce the formation of bone.

6. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '625 in view of U.S. Patent No. 5,868,745 to Alleyne.

Cauthen discloses the claimed invention except for the device being prepared in a color different than the viscera and skeletal tissue. Alleyne teaches that surgical devices may be provided in contrasting colors to differentiate them from the surrounding tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Cauthen with a contrasting color in order to differentiate the device from the surrounding tissue.

7. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen '625 in view of Eisermann et al. '750 as applied to claims 6-11 above, and further in view of Alleyne '745.

Cauthen, as modified, discloses the claimed invention except for the device being prepared in a color different than the viscera and skeletal tissue. Alleyne teaches that surgical devices may be provided in contrasting colors to differentiate them from the surrounding tissue. It would have been obvious to one having ordinary skill in the art at the time the

invention was made to provide the device of Cauthen, as modified, with a contrasting color in order to differentiate the device from the surrounding tissue.

8. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Harren et al. '562 in view of Alleyne '745.

Harren discloses the claimed invention except for the device being prepared in a color different than the viscera and skeletal tissue. Alleyne teaches that surgical devices may be provided in contrasting colors to differentiate them from the surrounding tissue. It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide the device of Harren with a contrasting color in order to differentiate the device from the surrounding tissue.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R. Baxter whose telephone number is 571-272-4691. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jessica R Baxter  
Examiner  
Art Unit 3733

*jrb*  
*jb*

*CZ*  
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